

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF GEORGIA  
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004
		4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
		Case Nos.
LIABILITY LITIGATION	*	4:13-cv-195 (M. Cole)

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O R D E R

Plaintiff Melanie Grubbs Cole filed this action against Defendant Mentor Worldwide LLC in the United States District Court for the District of Minnesota. The Judicial Panel on Multidistrict Litigation transferred her action to this multidistrict litigation proceeding. Upon completion of the pretrial proceedings in this action, the parties did not agree to a waiver of venue under *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). The Court thus cannot conduct the trial of this action in the United States District Court for the Middle District of Georgia, and the Court suggests that Plaintiff Melanie Grubbs Cole's action against Mentor be remanded to the United States District Court for the District of Minnesota. This Order contains a brief chronicle of the coordinated proceedings to provide guidance to the transferor court after remand.

**I. Brief Background of the Mentor ObTape MDL**

Mentor Worldwide LLC manufactured and sold a polypropylene mesh suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. The United States Food and Drug Administration cleared ObTape for sale in 2003 via its 510(k) regulatory process, and ObTape remained on the market in the United States until March 2006.

Several years ago, women who had been surgically implanted with ObTape began filing lawsuits against Mentor, alleging that they had been injured by ObTape—primarily that they suffered infections caused by ObTape and that they were injured when ObTape eroded through their bodily tissues. In December 2008, the Judicial Panel on Multidistrict Litigation created MDL No. 2004 and transferred seventeen actions involving alleged injuries resulting from ObTape to this Court for consolidated and coordinated pretrial proceedings. *See In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 588 F. Supp. 2d 1374 (J.P.M.L. 2008). After pretrial proceedings and a bellwether trial that settled mid-trial, the original cases and approximately forty additional tag-along cases transferred to this Court were resolved through settlement. Since then, MDL No. 2004 has grown to include nearly 800 additional tag-along cases, almost 400 of which remain open.

The litigation was divided into separate phases, and cases from phases IV and V are still pending. In 2013, the Court tried a Phase III bellwether case to verdict, and a Phase IV bellwether trial is scheduled to begin on November 30, 2015.

## **II. Overview of Cole's Case**

Plaintiff Melanie Grubbs Cole alleges that she suffered various injuries that she attributes to ObTape, including recurrent incontinence, infections, and pain. Cole filed her Complaint in the United States District Court for the District of Minnesota on June 5, 2013. She is a North Carolina resident. Cole's case was designated as a Phase IV-1 case. Discovery closed in April 2015. Mentor filed a partial summary judgment motion, which the Court granted, applying Minnesota law. *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, MDL Docket No. 2004, 2015 WL 6126829, at \*3 (M.D. Ga. Oct. 16, 2015); ECF No. 41 in 4:13-cv-195. All common discovery and coordinated pretrial proceedings in Cole's case are complete, and the case is ready for trial. The only claim that remains pending for trial is Cole's claim for negligence. *Id.*

## **CONCLUSION**

As discussed above, the Court suggests that this action be remanded to the United States District Court for the District of Minnesota. For the convenience of that court, the Court compiled a list of significant filings and orders in the Cole

case and in MDL No. 2004. That list appears as an appendix to this Order.

The Clerk of the Court shall provide a copy of this Order to the Clerk of the Judicial Panel on Multidistrict Litigation.

IT IS SO ORDERED, this 30th day of October, 2015.

S/Clay D. Land

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CLAY D. LAND

CHIEF U.S. DISTRICT COURT JUDGE  
MIDDLE DISTRICT OF GEORGIA

## APPENDIX

The Court compiled a list of significant filings and orders in this case and in MDL No. 2004:

### I. Significant Filings Specific to Melanie Grubbs Cole

1. Plaintiff Melanie Grubbs Cole's Complaint, June 5, 2013. ECF No. 1 in 4:13-cv-195.
2. Certified Copy of Conditional Transfer Order No. 74, June 24, 2013. ECF No. 5 in 4:13-cv-195.
3. Answer to Plaintiff Cole's Complaint, with Jury Demand, July 15, 2013. ECF No. 10 in 4:13-cv-195.
4. Scheduling/Discovery Order Designating Cole as a Phase IV-1 Case, Nov. 24, 2014. ECF No. 19 in 4:13-cv-195; ECF No. 877 in 4:08-md-2004. See also Amended Scheduling/Discovery Order, March 16, 2014. ECF No. 23 in 4:13-cv-195; ECF No. 905 in 4:08-md-2004 (modifying deadlines).
5. Order Granting Mentor's Motion for Partial Summary Judgment, Oct. 16, 2015. ECF No. 41 in 4:13-cv-195; 2015 WL 6134397. Granted summary judgment as to Cole's claims for breach of warranty, strict liability design defect, and strict liability failure to warn. **The only claim that remains pending for trial is Cole's negligence claim.**
6. Notice Regarding *Lexecon*, Oct. 23, 2015. ECF No. 42 in 4:13-cv-195. States that Mentor does not agree to waive *Lexecon*.

### II. Other Documents Relevant to Cole's Action

These documents are, for the most part, evidentiary rulings that were made in the context of the bellwether cases that were tried in this Court; these issues may arise again in Cole's case.

1. Order Denying Motion to Disqualify Expert Witness Dr. Catherine Ortuno, Apr. 1, 2010. ECF No. 231 in 4:08-md-2004; 2010 WL 1416548.

**Summary:** Mentor sought to exclude the testimony of Dr. Catherine Ortuno, who was an employee of a French Mentor subsidiary called Porges. While she was employed by Porges, Dr. Ortuno and a colleague developed concerns about the safety of ObTape and ultimately recommended that sales of ObTape be stopped. The Court concluded that Dr. Ortuno would be permitted to serve as an expert witness for Plaintiffs but that she would not be permitted to offer any testimony that would divulge privileged, attorney-client communications.

2. Order on Phase I Summary Judgment Motions and Admissibility of Plaintiffs' Experts, Apr. 22, 2010. ECF No. 241 in 4:08-md-2004; 711 F. Supp. 2d 1348.

**Summary:** Mentor sought to exclude Plaintiffs' experts under Federal Rule of Evidence 702.

**Dr. Catherine Ortuno** - motion denied; the Court found that Dr. Ortuno's methodology was sufficiently reliable.

**General Causation Witnesses** (Dr. Linda Brubaker, Dr. Suzanne Bush, Dr. Michel Cosson, Dr. John Davis, Dr. James Hiller, Dr. Mickey Karram, Dr. Kenneth Mitchell, Dr. Donald Ostergard, Dr. William Porter, and Dr. Andrew Siegel) - motion denied; the Court found that these experts' methodology was sufficiently reliable.

**Specific Causation Witnesses** (Dr. Linda Brubaker, Dr. Suzanne Bush, Dr. John Davis, Dr. James Hiller, Dr. Mickey Karram, Dr. Kenneth Mitchell, and Dr. Mark Slack) - motion denied; the Court found that these experts' methodology was sufficiently reliable.

**Dr. George Samaras** - motion granted in part and denied in part; based on then-existing Rule 26 Report, the Court concluded that Dr. Samaras would be permitted to testify on general causation but not specific causation.

**Dr. Ahmed El-Ghannam** - motion denied; the Court found that Dr. El-Ghannam's opinions were sufficiently reliable.

**Dr. Paul Ducheyne** - motion granted in part and denied in part; based on then-existing Rule 26 Report, the Court concluded that Dr. Ducheyne could not testify regarding what caused degradation in ObTape but could testify that Mentor should have done more testing based on Mentor's awareness that ObTape could degrade.

**Dr. Arnold Lentnek** - motion deferred pending *Daubert* hearing. On May 12, 2010, the Court decided to permit Dr. Lentnek's testimony (ECF No. 301 in 4:08-md-2004).

3. Order re Evidence Related to FDA Regulatory Process, Apr. 23, 2010. ECF No. 242 in 4:08-md-2004; 2010 WL 1734638.

**Summary:** Plaintiffs sought to exclude evidence related to the FDA regulatory process. Discussed basic rules regarding evidence of FDA regulatory process. Deferred ruling until pretrial conference. At the pretrial conference on May 3, 2010, the Court granted the motion in limine but stated that if Plaintiffs opened the door to the FDA evidence, it could come in. (ECF No. 299 - Transcript 174:9-175:16).

**Note:** this ruling was in the context of a strict liability claim under Georgia law, not a negligence claim. During the 2013 trial of *Morey v. Mentor*, 4:11-cv-5065, the Court admitted FDA 510k clearance evidence because the plaintiff in that case asserted a negligence claim under Minnesota law, and the evidence was relevant on that claim. The Court gave a limiting instruction on this issue. *Morey*, Jury Instructions Charge No. 11, ECF No. 183 in 4:11-cv-5065.

4. Order re Phase I Plaintiffs' Experts, Apr. 27, 2010. ECF No. 246 in 4:08-md-2004; 2010 WL 1727828.

**Summary:** Mentor sought to exclude the testimony of Plaintiffs' experts under Federal Rule of Evidence 702 and based on relevance. The motion was granted in part and denied in part.

**Dr. Ann Buchholtz** - testimony not permitted.

**Rabbit Study** - testimony explaining rabbit study permitted, but not testimony that rabbit study establishes that ObTape is capable of causing similar conditions in humans.

**Mentor's Warnings to Physicians and the FDA** - testimony may be relevant to failure to warn claim, but Plaintiff must establish relevance before eliciting this testimony.

5. Order re Phase I Experts, Apr. 29, 2010. ECF No. 282 in 4:08-md-2004; 2010 WL 1782272.

**Summary:** The parties sought to exclude expert testimony of each other's experts under Federal Rule of Evidence 702. The motions were denied.

**Dr. Michael Chernick** (Plaintiffs' statistician) - testimony permitted.

**Mentor's Specific Causation Rebuttal Witnesses** (Dr. Marta Villarraga, Dr. Charles L. Secrest, Dr. A.W. Karchmer, Dr. James M. Anderson) - testimony permitted.

**Dr. Marta Villarraga** (Mentor's expert re Mentor's conduct in bringing ObTape to Market) - testimony permitted.

**Mentor's Experts regarding Pore Distribution** (Drs. Villarraga and Clevenger) - testimony permitted.

6. Phase I Bellwether Pretrial Conference Transcript (Day 1), May 3, 2010. ECF No. 299 in 4:08-md-2004. Ruled from the bench on several motions in limine.

**Significant Issues:**

*Cross Motions to Exclude Evidence re FDA Regulatory Process* (ECF Nos. 249 & 259) - Granted. Hr'g Tr. 164:11-175:16. But see *supra* § III(B)(3).

*Plaintiffs' Motion to Exclude "Complication Rates"* (ECF Nos. 250 & 251) - Denied. Hr'g Tr. 175:20-178:19.

7. Phase I Bellwether Pretrial Conference Transcript (Day 2), May 4, 2010. ECF No. 300 in 4:08-md-2004. Ruled from the bench on several motions in limine.

**Significant Issue:**

*Mentor's Motion to Exclude Evidence Adverse Event Reports* (ECF No. 273) - Denied, but reports must be redacted. Hr'g Tr. 42:7-47:8.

8. Order re Dr. Arnold Lentnek, May 12, 2010. ECF No. 301 in 4:08-md-2004.

**Summary:** Denied Mentor's motion to exclude Dr. Lentnek, concluding that Dr. Lentnek's methodology was sufficiently reliable.



9. Order to "Tie Up Some Loose Ends" after Pretrial Conference, May 18, 2010. ECF No. 335 in 4:08-md-2004, 2010 WL 1998166.

**Summary:** addressed several issues. Significantly, the Court stated that it would permit recording of the testimony of European witnesses so the recordings could be used in later trials of MDL No. 2004 cases. Also addressed the trial structure and concluded that trial should be bifurcated (Phase 1: compensatory damages/punitive damages entitlement; Phase 2: punitive damages amount).

**Note:** part of this Order was later vacated (see ECF 350 re continuing duty to warn under Georgia law).

10. Order re Subsequent Remedial Measure, May 20, 2010. ECF No. 341 in 4:08-md-2004, 2010 WL 2015146.

**Summary:** Concluded that Mentor's decision to stop selling ObTape is a subsequent remedial measure under Federal Rule of Evidence 407, so evidence of this decision is not admissible "to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction" but may be admitted for another purpose. Also concluded that Mentor's introduction of a new sling product, Aris, was not a subsequent remedial measure under Federal Rule of Evidence 407.

11. Order re Similar Complications, May 28, 2010. ECF No. 351 in 4:08-md-2004, 2010 WL 2196632.

**Summary:** Explained rationale for concluding that Plaintiffs' evidence of other incidents were substantially similar to Plaintiffs' injuries.

12. Order Appointing Plaintiffs' Liaison Counsel and Co-Lead Counsel, Sept. 21, 2011. ECF No. 422 in 4:08-md-2004.

13. Order Establishing Plaintiffs' Litigation Expense Fund and Common Benefit, Aug. 9, 2012. ECF No. 493 in 4:08-md-2004. This agreement is between Plaintiffs' counsel and addresses the sharing among Plaintiffs of the cost of special services performed and expenses

performed for the common benefit of the Plaintiffs of MDL No. 2004.

14. Order re application of Minnesota law to non-Minnesota plaintiffs who file their actions in Minnesota. *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, No. 4:08-md-2004, 2013 WL 286276, at \*7 (M.D. Ga. Jan. 24, 2013).
15. Text Order re Dr. Ahmed El-Ghannam, June 4, 2013 in *Morey v. Mentor*, 4:11-cv-5065. Explained that general causation witness's must be tied to the Plaintiff: "To introduce [Dr. El-Ghannam'] testimony regarding ObTape degradation and/or the release of toxins, the witness must establish a causal connection between that degradation and/or release of toxins and Plaintiff's infection and extrusion/erosion."
16. Order re Post-Injury Evidence/Punitive Damages (in *Morey v. Mentor*), June 12, 2013. ECF No. 671 in 4:08-md-2004.  
  
**Summary:** Concluded that, under Minnesota law, certain post-injury evidence is admissible on the issue of punitive damages.
17. Order re Withdrawal of ObTape from the Market (in *Morey v. Mentor*), June 12, 2013. ECF No. 673 in 4:08-md-2004.  
  
**Summary:** Reiterated that the withdrawal of ObTape from the market was a subsequent remedial measure under Federal Rule of Evidence 407.
18. Jury Instructions and verdict form in *Morey v. Mentor*, June 13, 2013. ECF No. 183 in 4:11-cv-5065. **Note:** Morey asserted a negligence claim under Minnesota law.